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In Re: Patent Term Extension
Application for
U.S. Patent No. 6,740,669

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,740,669, claims of which cover the human drug product BANZEL® (rufinamide), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 819 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of a request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 819 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of September 4, 2009 (74 Fed. Reg. 45864), would be 1,365 days. Under 35 U.S.C. § 156(c):

Period of Extension	=	RRP - PGRRP - DD - ½ (TP - PGTP)[1]
	=	6,595 days - 4,960 - 0 - ½ (5,501 - 4,960 days)
	=	1,365 days (3.7 years)

Since the regulatory review period began October 27, 1990, before the patent issued (May 25, 2004), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From October 27, 1990, to and including May 25, 2004, is 4,960 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due

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[1] Consistent with 35 U.S.C. § 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on which the patent issued, "DD" is the number of days of the RRP that the applicant did not act with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and "PGTP" is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of ½ (TP - PGTP).

diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation, because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,365 days, would extend the patent from August 17, 2020, to May 13, 2024, which is beyond the 14-year limit (the approval date is November 14, 2008, thus the 14 year limit is November 14, 2022). The period of extension is thus limited to November 14, 2022, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, August 17, 2020, to and including November 14, 2022, or 819 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,740,669
Granted:	May 25, 2004
Original Expiration Date[2]:	August 17, 2020
Applicant:	Robert Portmann et al.
Owner of Record:	Novartis AG
Title:	Crystal Modification Of 1-(2,6-Difluorobenzyl)-1H-1,2,3-Triazole-4-Carboxamide And Its Use As Antiepileptic
Product Trade Name:	BANZEL® (rufinamide)
Term Extended:	819 days
Expiration Date of Extension:	November 14, 2022

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7728

[2]Subject to the provisions of 35 U.S.C. § 41(b).

Telephone inquiries related to this determination should be directed to Raul Tamayo at (571) 272-7728.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: BANZEL® (rufinamide)
Docket No.: FDA-2009-E-0056